Frequently Asked Questions concerning APHIS/CDC Form 2 Transfers

General questions about transferring a select agent or toxin

What is the purpose of an APHIS/CDC Form 2?

You use an APHIS/CDC Form 2 to request authorization to transfer a select agent or toxin. It also provides documentation of the transfer. By regulation, an APHIS/CDC Form 2 must be completed for each transfer of select agent(s) or toxin(s) and maintained for three years.

Is a transfer authorization from APHIS or CDC needed for intra-entity transfers?

No. But an "intra-entity transfer" is limited to those instances where a select agent or toxin is moved from one location within an entity to another (e.g., A Principal Investigator transferring part of his select agent inventory to another Principal Investigator from the same entity). The entity doing an intra-entity transfer must create a record of the intra-entity transfer that must include the following information: the select agent or toxin, quantity, date, sender, and recipient. By regulation, the record has to be maintained for a minimum of three years. If an entity does intra-entity transfers, its security plan must include a protocol for intra-entity transfers including chain-of-custody documents and provisions for safeguarding against theft, loss, or release. For more information regarding intra-entity transfers, refer to the "Select Agent and Toxins Security Document" at http://www.selectagents.gov/resources/Security%20Information%20Document.pdf.

Is a transfer authorization from APHIS or CDC needed to transfer toxins in a quantity below the regulated amounts?

No - IF the transfer meets all the other requirements of the exemption. A transfer authorization is not needed for toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor if the aggregate amount does not exceed the following amounts: Abrin 100 mg, Conotoxin 100 mg, Diacetoxyscirpenol 1000 mg, Ricin 100 mg, Saxitoxin 100 mg, Shiga-like ribosome inactivating proteins 100 mg, Tetrodotoxin 100 mg, Botulinum neurotoxin 0.5 mg, Staphylcoccal enterotoxin 5 mg, Clostridium perfringens epsilon toxin 100 mg, Shigatoxin 100 mg, T-2 toxin 1000 mg. All of the criteria of the exemption must apply before the exemption is effective.

Is a transfer authorization from APHIS or CDC needed to transfer attenuated strains of select agents that have been excluded by APHIS or CDC from the Select Agent Regulations?

No. The regulations establish a procedure by which APHIS or CDC may exclude an attenuated strain of a select biological agent or toxin when APHIS or CDC determine that the agent or toxin does not pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The list of APHIS and CDC approved attenuated strains can be found on the NSAR website at http://www.selectagents.gov/exclusions.htm. If an attenuated strain of a select biological agent or toxin is not listed at http://www.selectagents.gov/exclusions.htm, the agent or toxin is still a select agent or toxin and would need a transfer authorization from APHIS or CDC.

How do I submit a transfer request (APHIS/CDC Form 2)?

You may submit your transfer request to APHIS or CDC by mail, fax or email:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

Once submitted, when can I expect a decision regarding my transfer request?

A written decision from APHIS or CDC is usually provided within 72 hours of receipt of the request. However, please note that an APHIS/CDC Form 2 with incomplete or inaccurate information may delay a decision concerning your request.

How long is a transfer authorization from APHIS or CDC valid?

Approval of the transfer of a select agent and toxin is valid for 30 days from the date of authorization. This means that the transfer of the select agent or toxin must be completed before expiration of the 30 day period. Additionally, approval of a transfer becomes void should there be a change in any of the conditions upon which the approval was based (*e.g.*, change in the certificate of registration for the sender or recipient or change in the application for transfer). Each transfer authorization number is valid for only one transfer of select agents or toxins during the 30 day period.

Is a transfer authorization from APHIS or CDC needed to import a select agent or toxin into the United States?

Yes. Only individuals or entities registered with the CDC or APHIS for that specific select agent or toxin can legally import select agents and toxins; and only after they have received prior approval from APHIS or CDC. Also:

A. Importation of select agents or toxins may require the intended recipient to obtain a valid USDA and/or PHS permit prior to the transfer (See 7 CFR Part 330.200, 9

CFR Part 122.2, and 42 CFR Part 71.54) The application and instructions for obtaining USDA import permits are available through the APHIS website at: http://www.aphis.usda.gov/import_export/index.shtml or the Plant Pest Program (PPQ) website at: www.aphis.usda.gov/ppq/permits/ or by calling 301-734-5960. The application and instructions for obtaining PHS import permits are available through the CDC website at: www.cdc.gov/od/eaipp/ or by calling 404-718-2077.

B. The importer must be registered with CDC or APHIS for the select agent or toxin being imported and in accordance with 42 CFR 73.16, 9 CFR 121.16 and 7 CFR 331.16 must complete sections 1 and 2 of APHIS/CDC Form 2. A copy of the USDA or PHS permit should be included with the transfer request. Upon receipt of the select agent or toxin, the importer should submit section 3 of the APHIS/CDC Form 2 to APHIS or CDC.
C. The sender must comply with all applicable laws concerning packaging and shipping.

Is a transfer authorization from APHIS or CDC needed to transfer a presumptive select agent or toxin identified in a clinical/diagnostic laboratory specimen?

Anyone may send a presumptive select agent to a reference laboratory for confirmation without a transfer authorization from APHIS or CDC. However, after identity of the select agent or toxin is confirmed, a non-registered entity would be required to either destroy the specimen (diagnostic sample containing the isolate) or any isolates, or transfer it to an entity registered for that select agent or toxin. That transfer must first be authorized by either APHIS or CDC. To initiate the transfer process, contact a registered entity to arrange for transfer of your sample. If you need assistance locating a registered entity, contact APHIS (phone: 301-734-5960; fax: 301-734-3652) or CDC (phone: 404-718-2000; fax: 404-718-2096). For further guidance regarding reporting requirements for the identification of a select agent or toxin contained in a clinical/diagnostic laboratory specimen, please refer to: http://www.selectagents.gov/cdForm.htm.

Is a transfer authorization from APHIS or CDC needed to transfer a select agent or toxin that is contained in a specimen for proficiency testing?

No. A sponsor/sender may send a select agent or toxin that is contained in a specimen for proficiency testing to a recipient without obtaining prior authorization from APHIS or CDC provided that, at least seven calendar days prior to the transfer, the sponsor/sender send APHIS or CDC a written report that includes the select agent or toxin to be transferred and the name and address of the recipient. For further guidance on reporting the identification of a select agent or toxin contained in a proficiency test, please refer to: http://www.selectagents.gov/cdForm.htm.

General questions about completing the APHIS/CDC Form 2

Can the Alternate Responsible Official (ARO) sign the APHIS/CDC Form 2 if the Responsible Official (RO) is unavailable?

Yes. The ARO can sign the APHIS/CDC Form 2 if he or she is acting as the RO in RO's absence. However, the RO's name should be entered in Section A, Box 9 of the form even if the ARO signs the form.

What do I put in Block 19 if I am not registered with APHIS or CDC?

For non-registered entities, it is acceptable to list the facility director or laboratory manager.

What address should be specified under Section A (Recipient Information) and Section B (Sender Information)?

For registered entities, the address specified should be the entity's complete address, exactly as it appears on their current certificate of registration. For non-registered entities, please provide the complete, legal address of your entity. Please do not use a P.O. Box.

After a transfer authorization is received from APHIS or CDC, what is required of the sender that wants to ship a select agent or toxin?

The sender must:

- Notify the Recipient of the expected shipment and document this notification in Section 2 of the form.
- Ensure the material is properly packaged, labeled, and shipped in accordance with all federal regulations.
- Ensure that the individual's information and description of the package are documented in Section 2 of the form.
- Send APHIS or CDC a copy of the completed APHIS/CDC Form 2 (Sections 1 and 2) prior to shipment and include a copy with the select agent package.

What does the Recipient need to do upon receipt of the select agent shipment?

- First, confirm that all the select agents and toxins listed on Section 2 of the form were received. Document any discrepancies and notify the sender and APHIS or CDC. If it is determined that there was a theft or loss during packaging or in transit, immediately contact APHIS (phone: 301-734-5960; fax: 301-734-3652) or CDC (phone: 404-718-2000; fax: 404-718-2096) and submit APHIS/CDC Form 3 "Report of Theft, Loss or Release of Select Agents and Toxins." More information about reporting a theft or loss of a select agent or toxin is available at: http://www.selectagents.gov/tlrForm.htm. If it is determined that the discrepancy is due to an administrative error, send an explanation of the error and a corrected

APHIS/CDC Form 2 to APHIS or CDC. Please note that all records associated with a transfer should be kept for three years.

- Inspect the package to verify that it is not damaged or leaking and that the material was packaged, labeled and shipped in accordance with Federal regulations. If the package is received damaged or leaking to the extent that a release of the select agent or toxin may have occurred, immediately contact APHIS (phone: 301-734-5960; fax: 301-734-3652) or CDC (phone: 404-718-2000; fax: 404-718-2096) and submit APHIS/CDC Form 3 "Report of Theft, Loss or Release of Select Agents and Toxins." More information about reporting a release of a select agent or toxin is available at: http://www.selectagents.gov/tlrForm.htm. The U.S. Department of Transportation also has reporting requirements for release of hazardous materials. Refer to the next section regarding Department of Transportation Hazardous Materials Regulations requirements.
- Complete the information for Section 3 (on page 2) of the APHIS/CDC Form 2 and send one copy to the sender and one copy to APHIS or CDC **within 2 business days of receipt**.
- If the package is not received with 48 hours of expected delivery time immediately contact APHIS (phone: 301-734-5960; fax: 301-734-3652) or CDC (phone: 404-718-2000; fax: 404-718-2096) and submit APHIS/CDC Form 3 "Report of Theft, Loss or Release of Select Agents and Toxins." More information about reporting a theft or loss of a select agent or toxin is available at: http://www.selectagents.gov/tlrForm.htm.

General questions about transport of select agents and toxins

What are some of the specific measures required to ensure that infectious substances are shipped safely?

Department of Transportation Hazardous Materials Regulations (49 CFR Parts 171-180)

The Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) has specific requirements for transporting infectious substances safely by motor vehicle, railcar, vessel, and aircraft. These requirements must be followed by domestic and international shippers and carriers. They also contain provisions on how to apply international regulations for hazardous materials. PHMSA's requirements for infectious substances are outlined below and explained in detail in the Department of Transportation (DOT) publication, "Transporting Infectious Substances Safely". This document is available at: https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting Infectious Substances Safely.pdf.

Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease to humans or animals when exposure to them occurs. Category A infectious substances have two shipping names: "Infectious substances, affecting humans (UN 2814)" or "Infectious substances, affecting animals (UN 2900)." Examples of Category A substances can be found in the DOT publication "Transporting Infectious Substances Safely". This document is available at: https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting Infectious Substances Safely.pdf.

Packaging of Category A Infectious Substances

Category A infectious substances must be shipped in a triple package that consists of a watertight primary receptacle or receptacles; a watertight secondary packaging (for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of the primary receptacles); and a rigid outer packaging which must be of adequate strength for its capacity, mass, and intended use. Page 29 of the DOT "Transporting Infectious Substances Safely" (https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting Infectious Substances Safely.pdf) document provides a diagram of how to properly package a Category A infectious substance. The maximum quantity of Category A infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum allowable quantity on passenger aircraft is 50 ml or 50 g.

Labeling of Category A Infectious Substances

The outer container of all Category A infectious substance packages must display the following on one side of the package:

- Sender's name and address
- Recipient's name and address
- Infectious substance label
- Proper shipping name, UN number, and net quantity of infectious substance
- Name and telephone number of person responsible for shipment
- Cargo Aircraft Only label when shipping over 50 ml or 50 g
- Class 9 label, including UN 1845, and net weight if packaged with dry ice and identified as Carbon Dioxide, solid

Category B Infectious Substances

Category B infectious substances are infectious substances not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. Category B infectious substances have the proper shipping name "Biological Substance, Category B" and the identification number UN 3373.

Packaging of Category B Infectious Substances

Category B infectious substances must be shipped in a triple package consisting of a leak proof primary receptacle or receptacles; leak proof secondary packaging (for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of the primary receptacles); and rigid outer packaging. Page 31 of the DOT "Transporting Infectious Substances Safely" (https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting Infectious Substances Safely.pdf) document provides a diagram of how to properly package a Category B infectious substance. The maximum quantity for a primary receptacle is 500 ml or 500g and outer packaging must not contain more than 4 L or 4 kg.

Labeling of Category B Infectious Substances

The outer container of all Category B infectious substance packages must display the following on one side of the package:

- Sender's name and address
- Recipient's name and address
- The words "Biological Substance, Category B"
- UN 3373 label
- Class 9 label, including UN 1845, and net weight if packaged with dry ice and identified as Carbon Dioxide, solid

Diagnostic/Clinical Specimens

Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals. Diagnostic specimens are usually assigned to UN3373 unless the source patient or animal has or may have a serious human or animal disease which can be readily transmitted form one individual to another, directly or indirectly and for which effective treatment and preventable measures are not usually available in which case they must be assigned to UN2814 or UN 2900 and shipped as a Category A infectious substance.

Packaging of Diagnostic/Clinical Specimens

Diagnostic and clinical specimens must be shipped in a triple package consisting of a leak proof primary receptacle or receptacles; leak proof secondary packaging (for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of the primary receptacles); and rigid outer packaging. Page 31 of the DOT publication "Transporting Infectious Substances Safely" (https://hazmatonline.phmsa.dot.gov/services/publication_documents/Transporting Infectious Substances Safely.pdf) document provides a diagram of how to properly package a Diagnostic Specimen. The maximum quantity for a primary receptacle is 500 ml or 500g and outer packaging must not contain more than 4 L or 4 kg.

Labeling of Diagnostic/Clinical Specimens

The outer container of all diagnostic/clinical specimen packages must display the following on one side of the package:

- Sender's name and address
- Recipient's name and address
- The words "Biological Substance, Category B"
- UN 3373 label
- Class 9 label, including UN 1845, and net weight if packaged with dry ice and identified as Carbon Dioxide, solid

Biological Products

The DOT regulations (49 CFR 173.134(a)(2), http://edocket.access.gpo.gov/cfr_2007/octqtr/pdf/49cfr173.134.pdf) describe a biological product as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals. These are products derived from living organisms that are manufactured and distributed in accordance with special licensing requirements, and are used either for prevention, treatment or diagnosis of disease in human or animals, or for development, experimental or investigational purpose. They include, but are not limited to, finished or unfinished products such as vaccines and diagnostic products.

Packaging, Labeling and Shipping of Biological Materials

A biological product that is suspected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned to UN 2814, UN 2900, or UN 3373 as appropriate and shipped and packaged in accordance with those criteria.

Biological products transported for final packaging, distribution, or uses by medical professionals are not subject to shipping regulations.

Genetically Modified Organisms and Micro-organisms

These are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. They are divided into the following categories:

1. Genetically modified microorganisms, which meet the definition of an infectious agent, must be classified as Category A or Category B and assigned UN 2814 or UN 2900.

2. Animals, which contain or are contaminated with genetically modified microorganisms or organisms that meet the definition of an infectious substance must not be transported by air unless exempted by the States concerned.
3. Genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment, must not be transported by air unless exempted by the States concerned.
4. Except when authorized for unconditional use by the states of origin, transit, and destination, genetically modified microorganisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction must be classified as Class 9.

Genetically modified organisms, which do not meet the definition of an infectious substance and which are not otherwise included under (a) to (d) above, are not subject to these regulations.

Packaging of Genetically Modified Organisms and Micro-organisms

These materials must be packaged in the same manner as Category B infectious substances except there are no testing requirements for the packaging. The maximum allowable quantity per primary receptacle is 100 ml or 100 g. There is no maximum net quantity per package.

Labeling of Genetically Modified Organisms and Micro-organisms

The outer container of a genetically modified organism and micro-organisms assigned to UN 3245 must have the following labels:

- Sender's name and address
- Recipient's name and address
- Class 9 label

Definitions of Watertight/Leakproof

Although the PHMSA's Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180), do not specifically define the terms "watertight" and "leakproof," these terms under the HMR essentially mean the receptacles and packaging are designed and constructed in a manner that does not permit a liquid material to enter or escape. These regulations are available electronically at the U.S. Government Printing Office's website at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=585c275ee19254ba07625d8c92fe925f&c=ecfr&tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl.

What happens if a package containing a select agent or toxin is lost or damaged during shipment?

Requirements for All Infectious Substances

The DOT regulations (49 CFR 171.15 and 171.16) require each person in physical possession of a hazardous material, including an infectious substance, to report specific types of transportation incidents that involve these materials. Immediate reporting by telephone to the National Response Center at 1-800-424-8802 is required for incidents where fire, breakage, spillage, or suspected contamination occurs that involves the shipment of infectious substances other than a patient specimen or regulated medical waste (*See* 49 CFR 171.15(b)(3)). In addition, a written report to DOT is required within 30 days of the discovery of the incident for any unintentional release of hazardous material from a packaging during transportation, including those covered under 49 CFR 171.15 (*See* 49 CFR 171.16(a)). DOT regulations also require packages that contain infectious substances to be accompanied by several forms of hazard communication, as applicable, as well as labeled to indicate the infectious hazard (*See* 49 CFR 172.432 for a depiction of the required label). This label currently includes a statement for reporting a damaged package.

The WHO "Guidance on Regulations for the Transport of Infectious Substances," January 2009, available at http://www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10/en/, also provides specific recommended procedures for spill cleanup. This guidance is available to the agencies that govern land, vessel, and air shipments. The recommended procedures reflect those contained in the *WHO Laboratory Biosafety Manual, Third Edition, 2004.* The manual can be found at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/.

Special Requirements for Select Agents

If a package containing select agents has not been received within 48 hours after the expected delivery time or has been damaged to the extent that a release of a select agent may have occurred, the recipient must immediately report this incident to CDC or APHIS. In addition to the initial reporting, the entity must follow up with a written report (APHIS/CDC Form 3 - Report of Theft, Loss, or Release of Select Agents and Toxins) within 7 calendar days of the incident. Specific guidance on this form is available at: http://www.selectagents.gov/tlrForm.htm. Additional guidance on specific scenarios which would require an entity to report a theft, loss, or release of a select agent to CDC or APHIS is available at: http://www.selectagents.gov/complianceAssistance.htm. Upon receipt of the report of the incident, APHIS or CDC will review the report to determine the appropriate action, which could include requesting additional information, administrative action, inspection, and/or referral to the Federal Bureau of Investigation for further investigation. If there is a threat to the public, APHIS or CDC will notify the appropriate local, state, and federal agencies.

What is the status of the Department of Health and Human Services' (HHS) Transportation Regulation (42 CFR 72: Interstate Shipment of Etiologic Agents)?

HHS has removed Part 72 of Title 42, Code of Federal Regulations because DOT already has in effect a more comprehensive set of regulations applicable to the transport of infectious substances in commerce. DOT harmonizes its transport requirements with international standards adopted by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods for the classification, packaging, and transport of infectious substances. Rescission of the HHS rule eliminated duplication of the more current DOT regulations that cover intrastate and international, as well as interstate, commercial transport.

What are the specific regulations that govern the shipment of infectious substances?

There are several domestic and international regulations that govern the shipment of infectious substances. These include:

Domestic Regulations

- **Department of Transportation. 49 CFR Part 171-180, Hazardous Materials Regulations**. Applies to the shipment of infectious substances in commercial transportation to, from, or within the United States. These regulations also authorize, with certain conditions and limitations, the commercial transportation of hazardous materials in accordance with the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), the International Maritime Dangerous Goods Code (IMDG Code), Transport Canada's Transportation of Dangerous Goods Regulations (Transport Canada TDG Regulations), and the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material (IAEA Regulations). *See* 49 CFR 171.12(a) and 49 CFR Part 171, Subpart C. Information on these regulations may be obtained by calling (800) 467-4922 (Toll free) or (202) 366-4488 from 9:00 AM to 5:00 PM Eastern time, or at: http://www.phmsa.dot.gov/hazmat.
- **United States Postal Service (USPS). 39 CFR Part 20, International Postal Service (International Mail Manual), and Part 111, General Information on Postal Service (Domestic Mail Manual).** Regulations on transporting infectious substances through the USPS are codified in Section 601.10.17 of the Domestic Mail Manual and Section 135 of the International Mail Manual. A copy of the Domestic and International Mail Manuals may be obtained from the Government Printing Office by calling Monday through Friday, 7:30 a.m. - 9:00 p.m. EST: (202) 512-1800 or (866) 512-1800 (Toll free). The Domestic Mail Manual is available at: http://pe.usps.com/text/dmm300/dmm300_landing.htm. The International Mail Manual is available at: http://pe.usps.gov/text/imm/welcome.htm.
- **Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens.** These

regulations provide minimal packaging and labeling for blood and body fluids when transported within a laboratory or outside of it. Information may be obtained from your local OSHA office or at: http://www.osha.gov/.

International Regulations

- **Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions). International Civil Aviation Organization (ICAO).** Applies to the shipment of infectious substances by aircraft and is recognized in the United States and by most countries worldwide. The HMR recognize and authorize the Technical Instructions as an alternative to complying with the HMR for packaging, marking, labeling, classifying, and describing hazardous materials transported by aircraft and by motor vehicle either before or after being transported by aircraft. See 49 CFR Part 171, Subpart C. A copy of these regulations may be obtained from the ICAO Document Sales Unit at (514) 954-8022, Fax: (514) 954-6769, E-mail: sales_unit@icao.int, or at: http://www.icao.int.
- **Dangerous Goods Regulations. International Air Transport Association (IATA).** These instructions are issued by an airline association, based on the ICAO Technical Instructions, and followed by most airline carriers. However they do not have official standing under the HMR. A copy of these regulations is available at: http://www.iata.org/index.htm or http://www.who.int/en/, or by contacting the IATA Customer Care office at: Tel: (514) 390-6726 or (800) 716-6326 (Toll free), Fax: (514) 874-9659, or E-mail: custserv@iata.org.
- **The International Maritime Dangerous Goods Code. International Maritime Organization (IMO).** This code is of mandatory application for all 155 contracting parties to the International Convention for the Safety of Life at Sea (SOLAS). Information on this code is available at: http://www.imo.org/home.asp.
- **The Letter Post Manual. Universal Postal Union (UPU).** This manual reflects the United Nations Recommendations using the ICAO provisions as the basis for shipments. The manual can be found at http://www.upu.int/acts/en/2_letter_en.pdf.

For transfers of infectious substances that require the pre-approval of a regulatory entity, what are the specific regulations that govern such transfers?

Regulations governing the transfer of biological agents are designed to ensure that possession of these agents is in the best interest of the public and the nation. These regulations require documentation of personnel, facilities, justification of need, and pre-approval of the transfer by a federal authority. The following regulations apply to this category:

- **Importation of Etiologic Agents of Human Disease. 42 CFR Part 71, Foreign Quarantine. Section 71.54, Etiological Agents, Hosts and Vectors.** This regulation requires a PHS import permit from the CDC for importation of etiologic agents, hosts or vectors of human disease. The regulation, application form, and additional guidance is available at: http://www.cdc.gov/od/eaipp/. Importation of select agents into the U.S. also requires the intended recipient to be registered with either the CDC or APHIS for the select agent or toxin, and submit an APHIS/CDC Form 2 to obtain approval to import the select agent prior to each importation event (see 42 CFR 73 and/or 9 CFR 121). More information regarding select agents is available at: http://www.selectagents.gov.
- **Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases and Other Materials Derived from Livestock, Poultry or Other Animal. 9 CFR Part 122. Organisms and Vectors.** The USDA, APHIS, Veterinary Services (VS) requires that a permit be issued prior to the importation or domestic transfer (interstate movement) of etiologic disease agents of livestock, poultry, and other animals. Information may be obtained at (301) 734-5960, or at: http://www.aphis.usda.gov/import_export/index.shtml. Importation of select agents into the United States also requires the intended recipient to be registered with either the CDC or APHIS and submit an APHIS/CDC Form 2 to obtain approval to import the select agent prior to each importation event (see 42 CFR 73 and/or 9 CFR 121). More information regarding select agents is available at: http://www.selectagents.gov.
- **Transportation of Live Animals Containing or Contaminated with an Infectious Substance. 49 CFR 173.196(c).** An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by PHMSA's Associate Administrator for Hazardous Materials Safety. Information on these regulations may be obtained by calling (202) 366-4433 or (800) 467-4922 (toll free) from 9:00 AM to 5:00 PM Eastern time, or at: http://www.phmsa.dot.gov/hazmat.
- **Importation of Plant Pests. 7 CFR Part 330, Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage.** This regulation requires a permit for movement into or through the United States, or interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained by calling (877) 770-5990 or at: http://www.aphis.usda.gov./ppq/permits.
- **Export of Etiologic Agents of Humans, Animals, Plants and Related Materials. Department of Commerce (DOC). 15 CFR Parts 730 to 799.** This regulation requires that exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material and products which might be used for culture of large amounts of agents, obtain an export license. Information may be obtained by calling the DOC Bureau of Export Administration at (202) 482-4811, or at: https://bxa.ntis.gov/, http://www.access.gpo.gov/bis/index.html, or http://www.bis.doc.gov/.
- **Transfer of HHS/Overlap Select Agents. 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins; Final Rule.** The CDC regulates the

possession, use, and transfer of select agents that have the potential to pose a severe threat to public health and safety. A select agent may only be transferred under the conditions described in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. The APHIS/CDC Form 2 and additional guidance is available at: http://www.selectagents.gov.

- **Transfer of USDA/Overlap Select Agents. 9 CFR Part 121, Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule.** The USDA, APHIS, Veterinary Services (VS) regulates the possession, use, and transfer of select agents that have the potential to pose a severe threat to animal health or animal products. A select agent may only be transferred under the conditions described in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. The APHIS/CDC Form 2 and additional guidance is available at: http://www.selectagents.gov.
- The movement of Plant Pests is regulated under two distinct and separate regulations: **7 CFR Part 331, Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule and 7 CFR Part 330, Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage**. The USDA, APHIS, Plant Protection and Quarantine (PPQ) regulates the possession, use, and transfer of select agents that have the potential to pose a severe threat to plant health or plant products. A select agent or toxin may only be transferred under the conditions described in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. The APHIS/CDC Form 2 and additional guidance is available at: http://www.selectagents.gov. In addition, 7 CFR Part 330, the movement of a Plant Pest, also requires a permit for movement into, or through the United States, or interstate of any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Additional guidance is available at: http://www.aphis.usda.gov/plant_health/.